K132085

Co-Innovation Biotech Co.,Ltd.

510(k) Summary

Date of Summary Preparation: 11/11/2013

1. Submitter's Identifications

Submitter: Co-Innovation Biotech Co.,Ltd.
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2. Name of the Device

NOV 1 2 2013

Recommended classification regulation: 21 CFR 862.1155

Device class: Class II
Panel: Clinical Chemistry (75)
Product code: LCX
Common Name: Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test
Proprietary names:

Co-Innovation One Step HCG Test Strip
Co-Innovation One Step HCG Test Cassette
Co-Innovation One Step HCG Test Midstream

3. The Predicate Devices

K071930 One Step HCG Urine Pregnancy Test

4. Device Description

Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test is a rapid sandwich immunoassay device designed for the qualitative determination of human chorionic gonadotropin (hCG) concentration in human urine samples, as an aid in the early detection of pregnancy. The test devices are in three different formats: Strip,Cassette and Midstream . Three test formats use identical strips and each test strip in the device consists of:

1. A conjugate pad contains colloidal gold conjugated with mouse monoclonal anti-β-HCG antibody specific to the beta subunit of hCG.
2. A nitrocellulose membrane which is striped with the mouse monoclonal anti-α-HCG antibody in the test line (T line) and goat anti-mouse IgG polyclonal antibody in the control line (C line).

The Cassette format has the same performance specifications as the Test Strip format. The

difference is that the urine sample is dispensed by dropper onto the sample well on the cassette.

The Midstream format has the same performance specifications as the Test Strip format. The difference is that the device is placed into the urine stream or dipped into the urine collection cup for 5 seconds.

5. Intended Use of Device

The Co-Innovation One Step HCG Test Strip is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

The Co-Innovation One Step HCG Test Cassette is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

The Co-Innovation One Step HCG Test Midstream is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use .

6. Comparison to Predicate Devices:

A summary comparison of features of the Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test and the predicate devices is provided in the following Table:

Item	Device	Predicate (K071930)
Indication for use	Qualitative detection of human chorionic gonadotropin ("HCG") in urine	Same
Intended Users	Over the Counter (OTC)	Over the Counter (OTC) Use and Prescription Use
Specimen	Urine	Same
Clinical cut-off	25mIU/mL	Same
Read time	5 minutes	Same
Storage	4 ~ 30 °C	Same
Test Principle	Colloidal Gold Immunoassay	Same
Traceability	WHO 3rd IS	Same
Format	Strip,cassette,midstream	Same
Antibodies	Monoclonal anti-β-HCG antibody , monoclonal anti-α-HCG antibody, goat anti mouse IgG polyclonal	Differ

	antibody	

The Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test is similar to the predicate device with intended use,clinical cut-off,read time,test principle,test format,etc.

Specific antibodies differ.

7. Standard/Guidance Document Referenced (if applicable):

Guidance for Over-the Counter (OTC) Human Chorionic Gonadotropin (HCG) 510(k)s
ISO 14971:2007 Medical devices - Application of risk management to medical devices

8. Test principles:

The assay tests the human chorionic gonadotropin (HCG) qualitatively in the urine specimen, using the double antibody sandwich method. Each test device contains mouse monoclonal anti-β-HCG antibody colloidal gold conjugate pre-dried on a pad.Mouse monoclonal anti-α-HCG antibody (on the Test Line) and goat anti mouse IgG polyclonal antibody (on the Control Line) are coated and immobilized on a Nitrocellulose membrane. During the test procedures, the intact hCG in the urine specimen reacts with the dye conjugate (mouse anti-β-HCG antibody-colloidal gold conjugate specific to the beta subunit of hCG) and form Ag-Abβ-Au complexes. Because of capillary and chromatographic effects of the Nitrocellulose membrane, the complexes migrate along the membrane to the α-HCG antibody line (T), form Abα-Ag-Abβ-Au complexes and remain captured in the T line. As a result a red colored band develops in T and the result is positive. If there is no HCG in the urine, there is no red band in the Test zone, indicating negative result. No matter if there's HCG in the urine specimen, when the complexes migrate along the Control zone, a red band must be developed in the C zone.

9. Antibody Information

Antibody	The biological source	The location	Specific target antigen
Monoclonal anti-β-HCG antibody	Mouse	Conjugate pad	Specific to the beta subunit of hCG
Monoclonal anti-α-HCG antibody	Mouse	Nitrocellulose membrane	Specific to the alpha subunit of hCG
goat anti mouse IgG polyclonal antibody	Goat	Nitrocellulose membrane	

10. Performance Data:

Precision

30 clinical samples from normal,nonpregnant females spiked with the HCG(traceable to WHO 3rd IS) at different concentration containing 0mIU/ml,12.5mIU/ml, 18.75mIU/ml, 25mIU/ml, 50mIU/ml, 100mIU/ml (All the concentration was determined by immunoassay of ELISA).The controls were blind coded.Separate sets of the blind coded were assigned. Samples were also randomized prior to testing.The study was conducted 3 runs /day and lasted 10 days and was

conducted by three hospital laboratories . There are 3 batches Co-Innovation One Step HCG Test of three formats and each laboratory should conduct one batch separately. The midstream format were performed with both of these midstream test sample application methods (simulated midstream and dip). The result was recorded as the following:

The results of precision (strip)

HCG Concentration	LOT1		LOT2		LOT3	
	Positive	Negative	Positive	Negative	Positive	Negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	0	30	0	30	0	30
18.75mIU/ml	0	30	0	30	0	30
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0
100mIU/ml	30	0	30	0	30	0

The results of precision (cassette)

HCG Concentration	LOT1		LOT2		LOT3	
	Positive	Negative	Positive	Negative	Positive	Negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	0	30	0	30	0	30
18.75mIU/ml	0	30	0	30	0	30
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0
100mIU/ml	30	0	30	0	30	0

The results of precision (midstream,using the dip method)

HCG Concentration	LOT1		LOT2		LOT3	
	Positive	Negative	Positive	Negative	Positive	Negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	0	30	0	30	0	30
18.75mIU/ml	0	30	0	30	0	30
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0
100mIU/ml	30	0	30	0	30	0

The results of precision (midstream,using the simulated midstream method)

HCG Concentration	LOT1		LOT2		LOT3	
	Positive	Negative	Positive	Negative	Positive	Negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	0	30	0	30	0	30
18.75mIU/ml	0	30	0	30	0	30
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0

100mIU/ml	30	0	30	0	30	0

The results show that the precision of Co-Innovation One Step HCG Test in three batches of different formats are good.

Sensitivity study

According to the results of precision data above, the sensitivity of Co-Innovation One Step HCG Test is 25mIU/ml.

Specificity study

500mIU/ml LH(traceable to WHO 2nd IS)、1000mIU/ml FSH(traceable to WHO 2nd IRP) and1000uIU/ml TSH(traceable to WHO 2nd IRP) were spiked separately into the 60 urine specimen containing HCG at 0 mIU/ml and 25mIU/ml, respectively. 3 lots of samples were tested. According to the results, there's no cross reaction with LH at 500mIU/ml , FSH at 1000mIU/ml and TSH at 1000uIU/ml.

Study on the interfering substances

To evaluate the potential for interference by certain exogenous compounds, each compound was prepared by diluting stock interferent material to the desired concentration. Normal, nonpregnant females urine specimens containing 0 and 25 mIU/ml HCG were spiked with the interferents to obtain the desired test concentration. 3 batches of each format were tested. The results show that no interferences were observed from exogenous compounds at the following concentrations for both negative and positive HCG urine samples.

Interfering substances	Substances concentration
Acetaminophen	20mg/dL
Aspirin	20mg/dL
Ascorbic acid	20mg/dL
Atropine	20mg/dL
Caffeine	20mg/dL
Glucose	2000mg/dL
Hemoglobin	500mg/dL
Tetracycline	20mg/dL
Ampicillin	20mg/dL
Albumin	2000mg/dL
Bilirubin	2mg/dL

To evaluated the effects of the HCG β-core fragment ,normal,nonpregnant females urine specimens containing 0 and 25 mIU/ml HCG were spiked with the HCGβ-core fragment (traceable to WHO reference reagent 99/708) at the concentration of 125,000,250,000, 500,000 and 1,000,000 pmol/mL.3 batches of each format were tested. The above data show that there's no interference in the test result when the HCGβ-core fragment at the highest levels at which it is likely to be found in patient samples.

PH interference:

The pH of an aliquot negative urine pool is adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with HCG at 25mIU/ml and 0mIU/ml and 3 batches of Co-Innovation One Step HCG Test were tested repeatedly. The result demonstrate that varying ranged of PH do not interfere with the performance of the test.

Specific gravity interference:

Purified water and specimen with HCG 25mIU/ml were formulated into the solution with specific gravity at 1.01,1.02,1.03,1.04 separately. 3 lots of Co-Innovation One Step HCG Test were tested.The data show that there's no interference in the test result when the specific gravity is between 1.01-1.04.

Urinary system diseases interference:

Urine specimen which the items of white blood cells, red blood cells, urine occult blood, uric acid and urine ketone was/were strong positive were collected and for preparing the solution at HCG 0mIU/ml and 25mIU/ml. 3 lots of samples were tested repeatedly.The data show that the substance of leukocyte, erythrocyte, Urine occult blood, Urine acid or Ketone in the urine had no interference on the test result.

HOOK effect study

HCG free specimens spiked with the HCG at different concentration containing 62500mIU/ml, 125000mIU/ml, 250000mIU/ml, 500000mIU/ml, 1000000mIU/ml. Three lots of tests were tested.The results show that One Step HCG Test can get the positive result when the HCG concentration is range from 62,500 to 1,000,000mIU/ml, while the T line get to light as the concentration above 125000mIU/ml.

Professional method Comparison :

Urine samples were collected from 353 women at hospital laboratory to test for pregnancy. Approximately half of the women were pregnant in the early stage of less than 5 weeks (that meats less than 5 weeks since last menstrual period). Samples were randomly collected at various times throughout the day. Ages were from 18 to 45 years.Each specimen was blind coded.Separate sets of the blind coded were assigned.Samples were also randomized prior to testing.The tests performed by laboratory professionals were conducted at two laboratories (namely Professional A and Professional B). Each person tested the candidate device and the predicate device at the same time, but not sequentially.The data show that the agreement of Co-Innovation One Step HCG Test with the predicate device was 100%.

The results of professional method comparison (strip)

Candidate device		Predicate device Professional	
		Positive	Negative
Professional A	Positive	38	0
	Negative	0	42

Professional B	Positive	38	0
	Negative	0	42

The results of professional method comparison (cassette)

Candidate device		Predicate device Professional	
		Positive	Negative
Professional A	Positive	39	0
	Negative	0	74
Professional B	Positive	39	0
	Negative	0	74

The results of professional method comparison (midstream,using dip method)

Candidate device		Predicate device Professional	
		Positive	Negative
Professional A	Positive	37	0
	Negative	0	43
Professional B	Positive	37	0
	Negative	0	43

The results of professional method comparison
(midstream,using the simulated midstream method)

Candidate device		Predicate device Professional	
		Positive	Negative
Professional A	Positive	41	0
	Negative	0	39
Professional B	Positive	41	0
	Negative	0	39

The lay user method Comparison :

Urine samples were collected from 353 women at hospital laboratory to test for pregnancy. Approximately half of the women were pregnant in the early stage of less than 5 weeks (that meats less than 5 weeks since last menstrual period). Samples were randomly collected at various times throughout the day. Ages were from 18 to 45 years. These 353 layer users test their own urine using the English package insert as guide to perform the test.This included 80 layer users using test strip,113 using test cassette,160 using actual midstream method and the dip method

respectively for test midstream.They were asked to fill out an English questionnaire after finishing the test and collected samples for tests by laboratory professionals using the candidate devices. Each specimen was blind coded.Separate sets of the blind coded were assigned.Samples were also randomized prior to testing.The tests performed by laboratory professionals were conducted at a laboratory .

The results of the lay user method comparison (strip)

Candidate device		Candidate device Professional	
		Positive	Negative
Layer users	Positive	38	0
	Negative	0	42

The results of the lay user method comparison (cassette)

Candidate device		Candidate device Professional	
		Positive	Negative
Layer users	Positive	39	0
	Negative	0	74

The results of the lay user method comparison (midstream,using dip method)

Candidate device		Candidate device Professional	
		Positive	Negative
Layer users	Positive	37	0
	Negative	0	43

The results of the lay user method comparison
(midstream,using the actual midstream method)

Candidate device		Candidate device Professional	
		Positive	Negative
Layer users	Positive	41	0
	Negative	0	39

The performance tested by OTC user:

To evaluate its suitability to be used by the home use consumers (lay persons), spiked urine samples were tested by the lay persons and the results were compared with professional laboratory

results.The study was performed at 3 different point-of-care sites in Guangzhou, Shanghai and Wuhan.HCG free specimens spiked with the HCG (material traceable to WHO 3rd IS) at 18.75mIU/ml and 31.25mIU/ml. Both the concentration was determined by immunoassay of ELISA.Each concentration urine specimens were divided into 120 individual containers for a total of 240 aliquots. All aliquots were blindly labeled by a nonparticipant. Samples were also randomized prior to testing.240 female subjects with various education backgrounds and the ages from 18 to 45 participated in the lay user study. All of the subjects had no the experience of using the test before and were the untrained operators. Each subject conducted 1 test on one test format or one sample application method for the "midstream" using the English package insert as guide . Masked spiked urine were tested by professional laboratory personnel at the manufacturer site.The results show that Co-Innovation One Step HCG Test can be used by the untrained operator and get the correct results.

Results of performance tested by OTC user

Formats	Masked spiked sample		Masked spiked sample Professional users	
			+(31.25mIU/ml)	−(18.75mIU/ml)
Strip	Layer users	+(31.25mIU/ml)	29	0
		−(18.75mIU/ml)	1	30
Cassette	Layer users	+(31.25mIU/ml)	30	0
		−(18.75mIU/ml)	0	30
Midstream,using dip method	Layer users	+(31.25mIU/ml)	30	0
		−(18.75mIU/ml)	0	30
Midstream,using the simulated midstream method	Layer users	+(31.25mIU/ml)	30	1
		−(18.75mIU/ml)	0	29

11. Conclusion:

The results of evaluated studies demonstrate the substantial equivalency between Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test and the Predicate device. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate devices. The information supports substantial equivalence to the predicate device.

--- End of this section ---

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 12, 2013

CO-INNOVATION BIOTECH CO., LTD.
HONG FENG
PRODUCT MANAGER
NO. 13 YANYUAN ROAD, TIANHE DISTRICT
GUANGZHOU, GUANGDONG, CHINA 510507

Re: K132085
Trade/Device Name: Co-Innovation One Step HCG Test Strip
Co-Innovation One Step HCG Test Cassette
Co-Innovation One Step HCG Test Midstream
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: LCX
Dated: September 29, 2013
Received: October 2, 2013

Dear Ms. Feng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132085

Device Name: Co-Innovation One Step HCG Test Strip
Co-Innovation One Step HCG Test Cassette
Co-Innovation One Step HCG Test Midstream

Indications for Use:
The Co-Innovation One Step HCG Test Strip is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

The Co-Innovation One Step HCG Test Cassette is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

The Co-Innovation One Step HCG Test Midstream is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use .

Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k132085